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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,975	12/23/2003	Elena K. Davydova	EPICEN-09587	9377
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Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			EXAMINER BERTAGNA, ANGELA MARIE	
			ART UNIT 1637	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/743,975	<b>Applicant(s)</b> DAVYDOVA ET AL.	
	<b>Examiner</b> ANGELA BERTAGNA	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 83-94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2008 has been entered.

### ***Status***

2. Claims 83-94 are currently pending. In the response, Applicant amended claims 83, 85, 87, 91, and 93.

The following are new grounds of rejection. Any previously made rejections or objections not reiterated below have been withdrawn as being obviated by Applicant's amendments to the claims. Applicant's arguments that remain pertinent to the new grounds of rejection presented below have been fully considered, but they were not persuasive for the reasons set forth in the "Response to Arguments" section.

### ***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

Art Unit: 1637

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application Serial No. 10/153,219 and Provisional Application 60/292,845, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the '219 and '845 applications do not teach forming a transcription substrate by ligating two or more oligonucleotides to each other in a template-dependent process as required by claims 83 and 94, and therefore, they fail to adequately support the subject matter of claims 83-92 and 94. Also, the '219 and '845 applications do not teach that the target nucleic acid consists of a nucleic acid sequence tag joined to an analyte-binding substance and that the method further comprises forming a specific binding pair between an analyte and an analyte-binding agent prior to conducting step (b) in the method of claim 83, and therefore, they do not provide adequate support for the method of claims 88 and 92. Accordingly, claims 83-92 and 94 have only been granted benefit of Provisional Application 60/436,062, which was filed on **December 23, 2002**. Claim 93 does find adequate support in the prior-filed applications, and for this claim, an effective filing date of **May 22, 2001** has been used for prior art purposes.

Art Unit: 1637

***Specification***

4. The disclosure is objected to because of the following informalities: The continuity information appearing in the first paragraph of the specification should be updated to indicate that prior-filed Application Serial No. 10/153,219 has issued as US Patent No. 7,452,705.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 94 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94 is indefinite, because the relationship of the ligation product obtained in step (ii) of the method to the single-stranded DNA oligonucleotide used in step (b) of the method of claim 93 is unclear. Claim 94 is drawn to the method of claim 93, wherein step (b) of the method comprises providing a target nucleic acid and amplifying the target nucleic acid in a template-dependent process that comprises ligating two or more oligonucleotides using the target nucleic acid as a template. Step (b) of claim 93 recites "obtaining a single-stranded DNA oligonucleotide that contains a N4 virion RNA polymerase promoter sequence". It is not clear from the claim language whether steps (i) and (ii) of the method of claim 94 produce the single-stranded DNA oligonucleotide obtained in step (b) of claim 93 or if the ligation product obtained

Art Unit: 1637

in step (ii) of claim 94 is related in another way to the single-stranded DNA oligonucleotide of claim 93.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 83-85, 88, 89, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (EP 0 427 074 A2; cited previously) in view of Dai et al. (Genes & Development (1998) 12: 2782-2790; cited previously).

These claims are drawn to a method for making RNA that comprises ligating two or more oligonucleotides in the presence of a target nucleic acid to form a transcription substrate having a

Art Unit: 1637

single-stranded promoter and transcribing the ligation product with an RNA polymerase that lacks helicase-like activity and that can transcribe RNA using a single-stranded promoter.

Dattagupta teaches methods for making RNA that comprise template-dependent ligation of two oligonucleotides to produce a transcription substrate followed by transcription using an RNA polymerase (see abstract and Figure 5).

Regarding claim 83, Dattagupta teaches a method for making RNA using a target nucleic acid in a target nucleic acid as a template comprising:

(a) amplifying the target nucleic acid sequence in a template-dependent process that comprises ligating two or more oligonucleotides in the presence of the target nucleic acid, wherein at least one of the oligonucleotides comprises a single-stranded promoter that does not anneal to the target nucleic acid (see Figure 5 and page 8, lines 22-31); and

(b) transcribing the ligation product from step (a) with an RNA polymerase (see Figure 5 and page 8, lines 32-34).

Regarding claim 85, Dattagupta teaches that the method of claim 83 comprises (see Figure 5, page 8, lines 22-34, and Example 4 at page 13, lines 25-51):

(a) obtaining an RNA polymerase;

(b) obtaining DNA, wherein the obtaining comprises:

(i) providing a sample containing a target nucleic acid having a target nucleic acid;

(ii) annealing first and second probe oligonucleotides adjacently to each other on the target nucleic acid, wherein the first oligonucleotide contains a single-stranded RNA polymerase promoter sequence;

Art Unit: 1637

(iii) ligating the first and second probe oligonucleotides to one another to generate the DNA;

(c) admixing the RNA polymerase and the DNA; and

(d) culturing the RNA polymerase and the DNA, thereby generating RNA.

Regarding claims 88 and 92, Dattagupta teaches that the target nucleic acid consists of a target sequence tag that is joined to an analyte-binding substance, specifically a nucleic acid, and prior to performing step (b) in the method of claim 83, the method comprises (see page 7, lines 30-39):

(a) obtaining the analyte-binding substance to which the target sequence tag is joined;

(b) contacting the analyte-binding substance to which the target sequence tag is joined with the analyte (the immobilized probe sequence) to form a specific binding pair;

(c) removing the analyte-binding substance molecules that are not bound to the analyte from the specific binding pair; and

(d) providing the resulting specific binding pair.

Dattagupta does not teach using a polymerase that lacks helicase-like activity and that can transcribe RNA from a single-stranded promoter as required by claims 83-85, 88, 89, and 92. Dattagupta also does not teach that the RNA polymerase is an N4 virion RNA polymerase as required by claims 84, 85, and 89.

Dai analyzed the promoter requirements of the N4 virion RNA polymerase (see abstract and pages 2782-2783). Dai teaches that the N4 virion RNA polymerase lacks helicase-like activity and is capable of transcribing RNA using a single-stranded promoter (see abstract and page 2782). Dai further teaches that the N4 virion RNA polymerase transcribes hairpin promoter



Art Unit: 1637

structures in the presence of *E. coli* single-stranded binding protein (see page 2782 and pages 2787-2789).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize an N4 virion RNA polymerase when practicing the method of Dattagupta. Since Dattagupta taught performing the transcription step using an RNA polymerase that recognized a hairpin promoter (see page 5, lines 20-55, for example), an ordinary artisan would have been motivated to use any RNA polymerase known to possess this activity when practicing the method of Dattagupta recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, selection of a known material based on its suitability for the intended purpose is *prima facie* obvious in the absence of secondary considerations. Also, as noted in MPEP 2144.06, it is *prima facie* obvious to substitute art-recognized equivalents useful for the same purpose. In this case, as evidenced by the teachings of Dai cited above, the N4 virion RNA polymerase was known to be capable of transcribing RNA having a hairpin promoter in the presence of *E. coli* single-stranded binding protein. Therefore, an ordinary practitioner of the method taught by Dattagupta would have been motivated to utilize this RNA polymerase in the transcription step of the method with a reasonable expectation of success. Thus, the methods of claims 83-85, 88, 89, and 92 are *prima facie* obvious over Dattagupta in view of Dai.

8. Claims 83-92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (EP 0 427 074 A2; cited previously) in view of Kazmierczak et al. (WO 02/095002 A2; cited previously).

Art Unit: 1637

These claims are drawn to a method for making RNA that comprises ligating two or more oligonucleotides in the presence of a target nucleic acid to form a transcription substrate having a single-stranded promoter and transcribing the ligation product with an RNA polymerase that lacks helicase-like activity and that can transcribe RNA using a single-stranded promoter.

Dattagupta teaches methods for making RNA that comprise template-dependent ligation of two oligonucleotides to produce a transcription substrate followed by transcription using an RNA polymerase (see abstract and Figure 5).

Regarding claims 83 and 94, Dattagupta teaches a method for making RNA using a target nucleic acid in a target nucleic acid as a template comprising:

(a) amplifying the target nucleic acid sequence in a template-dependent process that comprises ligating two or more oligonucleotides in the presence of the target nucleic acid, wherein at least one of the oligonucleotides comprises a single-stranded promoter that does not anneal to the target nucleic acid (see Figure 5 and page 8, lines 22-31); and

(b) transcribing the ligation product from step (a) with an RNA polymerase (see Figure 5 and page 8, lines 32-34).

Regarding claims 85 and 94, Dattagupta teaches that the method of claim 83 comprises (see Figure 5, page 8, lines 22-34, and Example 4 at page 13, lines 25-51):

(a) obtaining an RNA polymerase;

(b) obtaining DNA, wherein the obtaining comprises:

(i) providing a sample containing a target nucleic acid having a target nucleic acid;

Art Unit: 1637

(ii) annealing first and second probe oligonucleotides adjacently to each other on the target nucleic acid, wherein the first oligonucleotide contains a single-stranded RNA polymerase promoter sequence;

(iii) ligating the first and second probe oligonucleotides to one another to generate the DNA;

(c) admixing the RNA polymerase and the DNA; and

(d) culturing the RNA polymerase and the DNA, thereby generating RNA.

Regarding claims 88 and 92, Dattagupta teaches that the target nucleic acid consists of a target sequence tag that is joined to an analyte-binding substance, specifically a nucleic acid, and prior to performing step (b) in the method of claim 83, the method comprises (see page 7, lines 30-39):

(a) obtaining the analyte-binding substance to which the target sequence tag is joined;

(b) contacting the analyte-binding substance to which the target sequence tag is joined with the analyte (the immobilized probe sequence) to form a specific binding pair;

(c) removing the analyte-binding substance molecules that are not bound to the analyte from the specific binding pair; and

(d) providing the resulting specific binding pair.

Dattagupta does not teach using a polymerase that lacks helicase-like activity and that can transcribe RNA from a single-stranded promoter as required by claims 83-85, 88, 89, and 92. Dattagupta also does not teach that the RNA polymerase is the N4 virion RNA polymerase as required by claims 84, 85, and 89. Dattagupta also does not teach using mini-vRNAP as the RNA polymerase as required by claims 86, 87, 90, 91, and 94.

Art Unit: 1637

Kazmierczak teaches a method for making RNA from a single-stranded DNA oligonucleotide containing an N4 virion RNA polymerase promoter using the transcriptionally active variant of the N4 virion RNA polymerase termed mini-vRNAP (see abstract).

Kazmierczak teaches that most DNA-dependent RNA polymerases require a double-stranded transcription substrate, thereby limiting methods of RNA synthesis to those in which a double-stranded DNA transcription substrate is available (page 2, paragraph 2). Kazmierczak teaches that the above N4 virion RNA polymerase is capable of transcribing RNA from a single-stranded promoter, a denatured double-stranded promoter, a double-stranded promoter, or a hairpin promoter (see page 2, paragraph 2, page 4, paragraph 1, page 4, last paragraph – page 5, first paragraph, and page 13, first paragraph).

Regarding claim 83, Kazmierczak teaches that the N4 virion RNA polymerase lacks helicase activity and transcribes RNA using a single-stranded promoter (page 13).

Regarding claims 84, 85, and 89, the method of Kazmierczak comprises using mini-vRNAP or the Y678F variant of mini-vRNAP to transcribe a single-stranded DNA oligonucleotide containing an N4 RNA polymerase promoter sequence (see page 3, last paragraph – page 4, second paragraph, for example).

Regarding claims 86 and 90, Kazmierczak teaches that mini-vRNAP is a single transcriptionally active protein that is approximately 1,100 amino acids in length and that corresponds to the middle 1/3 of the complete N4 virion RNA polymerase between amino acid 998 and amino acid 2103 of the full-length N4 virion RNA polymerase (page 69, paragraph 2).

Art Unit: 1637

Regarding claims 87 and 91, Kazmierczak teaches that the N4 virion RNA polymerase is a polypeptide having the amino acid sequence of SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8 (see page 4, paragraph 2).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize an N4 virion RNA polymerase taught by Kazmierczak when practicing the method of Dattagupta. An ordinary artisan would have been motivated to do so with a reasonable expectation of success, since Kazmierczak taught that the N4 virion RNA polymerase could transcribe single-stranded and double-stranded substrates, including hairpin promoters (see page 2, paragraph 2, page 4, paragraph 1, page 4, last paragraph – page 5, first paragraph, and page 13). An ordinary artisan would have recognized from these teachings of Kazmierczak that utilizing an N4 virion RNA polymerase in the method of Dattagupta would have provided the advantage of increased flexibility regarding the DNA substrate to be transcribed. An ordinary artisan also would have recognized that the N4 virion RNA polymerase taught by Kazmierczak was a suitable RNA polymerase for use in the method of Dattagupta, and therefore, would have been motivated to use it in the transcription step of the method with a reasonable expectation of success. As noted in MPEP 2144.07, the selection of a known material based on its suitability for the intended purpose is *prima facie* obvious in the absence of unexpected results. Thus, the methods of claims 83-92 and 94 are *prima facie* obvious over Dattagupta in view of Kazmierczak.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1637

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 93 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 29, 36, and 40 of copending Application No. 10/719,913.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 26, 29, 36, and 40 of the ‘913 application recite a species of the method generically claimed in the instant claim 93. Thus, the methods recited in claims 26, 29, 36, and 40 of the ‘913 application anticipate the method recited in the instant claim 93.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 93 is directed to an invention not patentably distinct from claims 26, 29, 36, and 40 of commonly assigned Application Serial No. 10/719,913. Specifically, as discussed above,

Art Unit: 1637

claims 26, 29, 36, and 40 of the '913 application recite a species of the method generically claimed in the instant claim 93. Thus, the methods recited in claims 26, 29, 36, and 40 of the '913 application anticipate the method recited in the instant claim 93.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Application Serial No. 10/719,913, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### ***Response to Arguments***

12. Applicant's arguments filed on October 23, 2008 that remain pertinent to the new grounds of rejection presented above have been fully considered, but they were not persuasive.

Regarding the rejection of claims 84, 85, and 89 under 35 U.S.C. 103(a) as being unpatentable over Dattagupta in view of Dai, Applicant argues that the amendments to the claims

Art Unit: 1637

obviate the rejection (see page 9). In particular, Applicant argues that the combined teachings of Dattagupta and Dai do not suggest that at least one of the two oligonucleotides used to form the ligation product comprises a single-stranded promoter that does not anneal to the target nucleic acid as required by independent claim 83. In view of the claim amendments, this rejection is currently applicable to claims 83-85, 88, 89, and 92. Applicant's arguments were not persuasive, because as discussed above, Dattagupta teaches ligation using an oligonucleotide having the claimed structural features (see Figure 5 and page 8, lines 22-31). The broadest reasonable interpretation of the limitation "an oligonucleotide comprising a single-stranded promoter that does not anneal to the target nucleic acid" excludes double-stranded promoters formed from two separate oligonucleotides, but includes hairpin promoters formed from a single-stranded oligonucleotide, such as the hairpin promoters taught by Dattagupta. Since Applicant's arguments were not persuasive, the rejection has been maintained.

Regarding the rejection of claims 84-87 and 89-91 under 35 U.S.C. 103(a) as being unpatentable over Dattagupta in view of Kazmierczak, Applicant argues that the Kazmierczak reference does not qualify as prior art. In particular, Applicant argues that the Kazmierczak reference was filed on the same day and contains the same disclosure as Application Serial No. 10/153,219, to which the instant application claims benefit under 35 U.S.C. 120 (see pages 9-10). In view of the claim amendments, this rejection is currently applicable to claims 83-92 and 94. Applicant's arguments were not persuasive, because the instant claims 83-92 and 94 are not entitled to the benefit of the earlier-filed '219 application. As discussed above, the effective filing date of claims 83-92 and 94 of the instant application is December 23, 2002. As a result, the Kazmierczak reference, which was published on November 28, 2002, qualifies as prior art



Art Unit: 1637

under 35 U.S.C. 102(a) and 35 U.S.C. 102(e). Claim 93 is the only claim in the instant application that is entitled to an effective filing date of May 21, 2001, and this claim has not been rejected citing the Kazmierczak reference (see above). Since Applicant's arguments were not persuasive, the rejection has been maintained.

### ***Conclusion***

13. No claims are currently allowable. It is noted that claim 93 is free of the art, but it has been rejected on the ground of provisional obviousness-type double patenting.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kazmierczak et al. (The European Molecular Biology Journal (2002) 21(21): 5815-5823) is cited as a reference of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

amb

/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637